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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,936	11/03/2003	Laura Gillim-Ross	DHI-07986	4323

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,936	GILLIM-ROSS ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005, 4/12/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-26 and 28-41* is/are pending in the application.

4a) Of the above claim(s) *36-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-26 and 28-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I in the reply filed on 7/5/2005 is acknowledged.

Claims 36-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/5/2005.

Claim Objections

Claims 1, 6, 18, and 24 are objected to because of the following informalities: Claim 1, line 2 is missing the word "of". Claim 6, 18, and 24 recite the abbreviation "pRHMK" without spelling out "primary rhesus monkey kidney" the first time the abbreviation is used in the claims. Appropriate correction is required.

Claims 10-12, 19, 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claims 10-12 depend from claim 6, which recites specific cells lines (or a specific type of primary cell). If the cells are transgenic, as required by claims 10 and 11, then they are no longer the same cells as recited in claim 6, and are outside the scope of claim 6. If the cells of claim 6 are "wild-type", then claim 12 provides no further limitation; if the cells of claim 6 are not "wild-type", then claim 12 is outside the scope of claim 6. If some of the claim 6 cell lines are "wild-type" and others are not, claim 12 would be clarified by simply reciting which cell line is intended.

For claims 19 and 31, these claims fail to further limit the parent claim, because the parent claim requires detecting the presence of a subgenomic RNA, but these claims require the opposite, detecting the absence of the subgenomic RNA.

Claim Rejections - 35 USC § 112

Claims 6-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that cell lines HEK-293T, Huh-7, and Mv1Lu are required to practice the claimed invention, because these are specifically recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of HEK-293T, Huh-7, and Mv1Lu.

The specification does not provide a repeatable method for obtaining these specific cell lines, and it does not appear to be readily available material.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claims 1-6, 8-26, 28-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, there is no step relating the "detecting" to the purpose set forth in the preamble. This affects dependent claims.

In claim 2, is the intent to require the subgenomic RNA to comprise a portion of a leader sequence, or is the intent to require a PCR primer comprising a portion of a leader sequence? Claim 15 is confusing because it calls for the assay to be performed with frozen cells, but the virus would not infect and produce subgenomic RNA while frozen. Claim 19 is confusing in being outside the scope of the parent claim; the parent claim requires "detecting the presence" of subgenomic RNA, while claim 19 requires the opposite, "detecting an absence." Claim 31 similarly depends from a claim requiring detecting RNA but specifies detecting an absence. Claim 33 lacks antecedent basis for "said second agent."

For claims 18-21 as written, the purpose of the assay is not apparent, why detect virus from two samples? What useful information is gained by determining that patient Smith's sample has more subgenomic RNA than patient Doe's sample, or that the Smith and Doe samples make different ratios of subgenomic/genomic RNAs? Are claims 18-23 actually meant to involve comparing the results of different treatments for one (divided) virus sample? This affects dependent claims.

Claim 24 is confusing, because it calls for detecting an altered level of SARS replication without any step of infecting the treated cells with SARS, and it does not state whether or not the "cells not treated with said first test agent" are the same kind of cells as the treated cells. This affects dependent claims/

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Thiel et al (Journal of General Virology 84:2305-2315, available 19 June 2003; IDS no. 61) or Snijder et al (Journal of Molecular Biology 331:991-1004, 20 August 2003; IDS no. 60). Figure 1d of Thiel shows PCR amplification of a subgenomic RNA comprising a leader sequence, and detection of the amplified product by sequence analysis. Figure 3B of Snijder shows detection of subgenomic RNAs with leader sequences. These meet each and every limitation of the claims.

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Yount et al (PNAS 100:12995-1300, available online October 20, 2003; IDS no. 70). See page 12998, first paragraph of column 2 for detection of a leader sequence; page 12998, last paragraph of column 1 for detection of genomic RNA; Figure 2B for detection of polypeptide; and the passage spanning pages 12997-12998 for detection of virus.

Claims 6, 8-26, 28-35 appear to be free of the prior art, because the art does not teach or suggest replicating SARS coronavirus in the cells lines listed in the claims. In regard to the pRHMK cells, some practitioners such as Zheng et al and Peiris et al (IDS no. 72, 53) were known to propagate SARS in fetal rhesus monkey kidney cells. However the prior art provides no particular motivation to substitute primary cells for a well-characterized cell culture line.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/17/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER